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भारतीय मानक

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(पहला पुनरोक्षण)

Indian Standard

SURGICAL INSTRUMENTS — GALL DUCT DILATORS, BAKE'S PATTERN — SPECIFICATION

(First Revision)

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BUREAU OF INDIAN STANDARDS MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG NEW DELHI 110002

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1977. It has been revised to include another type of gall duct dilator with cylindrical working end. Besides, it incorporates the approximate mass of various sizes of dilators and recognizes only stainless steel as material for dilators.

In the preparation of this standard, assistance has been derived from DIN 13456: 1982 'Medical instruments, gall duct dilators, type Bakes' issued by Deutsches Institut für Normung, Germany.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2: 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

SURGICAL INSTRUMENTS — GALL DUCT DILATORS, BAKE'S PATTERN — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard specifies the requirements for Bake's pattern gall duct dilators.

2 REFERENCES

2.1 The Indian standards listed below are necessary adjuncts to this standard:

IS No.

Title

6603:1972

Specification for stainless steel

bars and flats

7531:1990

Methods for testing of corrosion resistance of stainless steel surgical instruments (first

revision)

3 MATERIAL

3.1 The instrument shall be made of stainless steel conforming to designation 02Cr18Ni11 or 04Cr18Ni10 or 07Cr18Ni9 of IS 6603: 1972.

4 TYPES, SHAPE, DIMENSIONS AND MASS

- **4.1** The gall duct dilators shall be of two types, namely dilator with bulb type working end and dilator with cylindrical working end as shown in Fig. 1 and Fig. 2 respectively.
- **4.2** Sizes, dimensions and mass for dilator with bulb type working end shall be as shown in Fig. 1.
- 4.3 Sizes, dimensions and mass for dilator with cylindrical working end shall be as shown in Fig. 2.

5 WORKMANSHIP

5.1 The working end of the dilator shall be rounded and finished smooth.

6 SURFACE CONDITION

6.1 General

All surfaces shall be free from pores, crevices, seams, burrs and grinding marks. The instrument shall be supplied free from residual scale, acid, grease, grinding and polishing material.

6.2 Surface Finish

The instrument shall have a dull surface finish e.g. satin finish or matt finish.

6.3 Passivation and Final Treatment

The instrument shall be treated by a suitable passivation process, for example, electropolishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature not less than 10° C and not exceeding 60° C. The instrument shall then be rinsed in water and dried in hot air.

7 CORROSION RESISTANCE TEST

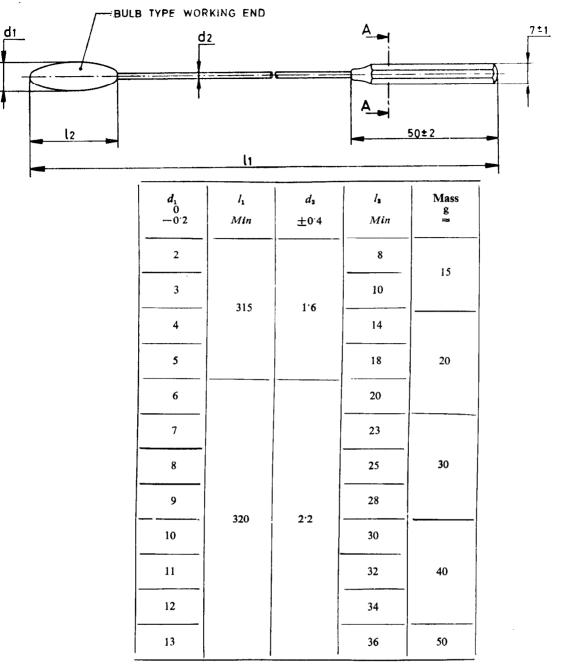
7.1 The instrument shall be tested for corrosion resistance in accordance with IS 7531: 1990. It shall pass the test.

8 MARKING

8.1 The instrument shall be marked legibly and indelibly with the identification of the source of manufacture, the letter 'SS' or the words 'Stainless Steel' and the country of manufacture.

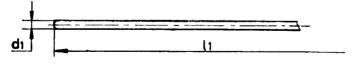
9 PACKING

9.1 The instrument shall be individually put either in a polyethylene bag or wrapped in wax paper. Each instrument shall then be packed in a carton as agreed to between the purchaser and the manufacturer or in accordance with the current trade practice.



All dimensions in millimetres

Fig. 1 DILATORS, GALL DUCT, BAKE'S PATTERN



| d ₁ 0 -0'2 | l ₁ Min | Mass g = |
|-----------------------------|-----------------------|----------------|
| 1.2 | 315 | 15 |

All dimensions in millimetres.

FIG. 2 CYLINDRICAL TYPE WORKING END

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The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

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